UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,336	11/13/2003	Paul Ashton	CDSI-P01-030	9868

28120 7590 12/20/2007

ROPES & GRAY LLP
PATENT DOCKETING 39/41
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	
MAIL DATE	**DELIVERY MODE**
12/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,336	ASHTON ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *2-11,18-20 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,12-17 and 21-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/14/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and Applicant's Arguments/Remarks and the request for extension of time (5 months-granted), all filed 10/09/07 is acknowledged.

Applicant's election of Group I (claims 1 & 12-37); Election of permeable member of claim 30: cross-linked polyvinyl alcohol; Election of impermeable member of claim 32: plasticized nylon; Election of antiviral agent of claim 15: nevirapine and Election of Effect of claim 20/21: local effect in the reply filed on 10/09/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2-11, 18-20 and 38 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/09/07.

Claims 1-38 are pending in this action. Claims 2-11, 18-20 and 38 have been withdrawn (non-elected invention). Claims 1, 12-17 and 21-37 are being examined in this action. Claims 1, 12-17 and 21-37 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 12-19 and 21-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,375,972 ('972 Patent). Although the conflicting claims are not identical, they are not patentably distinct from

each other because the '972 Patent also claims a sustained release drug delivery system that comprises an inner drug core comprising a therapeutically active agent; an inner tube impermeable to passage of agent, whereby the inner tube has first and second ends and covering at least a portion of said inner drug core, said inner tube being dimensionally stable; an impermeable member positioned at said inner tube first end, the impermeable member preventing passage of said agent out of said drug core through said inner tube first end; and a permeable member positioned at said inner tube second end, said permeable member allowing diffusion of said agent out of said drug core through said inner tube second end.

The only difference observed between the '972 Patent and the instant claims are that the '972 recites the generic "therapeutic agent" in claim 1, whereas instant claim 1 recites a specific class of therapeutic agent – "antiviral". The '972 additionally claims a "local or systemic physiological or pharmacological effect" in claim 1. However, note that claims 20 and 21 of the instant application also claims release of the active agent to provide a "local" and "systemic" effect. Asides from these distinctions, the inventions of the instant application and the '972 Patent are essentially similar.

* * * * *

Claims 1, 12-19 and 21-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 43, 46, 49, 50, 55, 58, 61, 63-67 and 70-74 of copending Application No. 10/096,877 ('877 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '877 application also claims a sustained release drug delivery system comprising a drug reservoir

comprising a therapeutically effective amount of an agent; an inner tube having first and second ends and covering at least a portion of said drug reservoir, said inner tube being dimensionally stable and capable of supporting its own weight; and an outer layer covering at least a portion of said drug reservoir and/or inner tube, wherein upon implantation, agent is released through at least one of the open ends.

The only difference observed between the '877 application and the instant claims are that the '877 application recites that the inner tube, aside from being dimensionally stable, is also "capable of supporting its own weight". Claim 1 of '877 also does not recite an impermeable member located at the inner tube, first end and does not recite a permeable member positioned at said inner tube first/second ends. However, note that claim 46 recites the limitation that the sustained release drug delivery system further comprises "an impermeable member positioned at said inner tube, first end". Also note claims 49 & 50, which recite the limitation that the sustained release drug delivery system further comprises "a permeable member positioned at said inner tube first/second ends". Instant claim 1 recites a specific class of therapeutic agent – "antiviral", whereas claim 1 of '877 is generic and recites "an agent". However, note that claim 70 of '877 claims that the agent is an "anti-viral agent". Asides from these distinctions, the inventions of the instant application and the '877 application are essentially similar.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 30-33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith *et al.* (U.S. Pat. No. 5,378,475).

Smith *et al.* ('475) disclose sustained release drug delivery devices and methods for treating a mammalian organism to obtain a desired local or systemic physiological or pharmacological effect. The device includes an inner core or reservoir comprising the effective agent; a first coating layer, which is essentially impermeable to the passage of the effective agent; and a second coating layer, which is permeable to the passage of the effective agent. the first coating layer covers at least a portion of the inner core; however, at least a portion of the inner core is not coated with the first coating layer. The second coating layer essentially completely covers the first coating layer and the uncoated portion of the inner core (see Abstract); (col. 1, lines 5-20).

Smith et al. teach that the first layer must be selected to be impermeable to the passage of the agent from the inner core out to adjacent portions of the second coating layer. The purpose is to block the passage of the agent to those portions and thus control the release of the agent out of the drug delivery device (col. 7, lines 10-33).

Natural or synthetic materials that can be used in the device include cross-linked polyvinyl alcohol, plasticized nylon, silicone rubbers and the like (col. 6, lines 41-66). See also column 8, lines 49-68).

The instant claims are anticipated by Smith *et al.*

* * * * *

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 12-17, and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Groenewegen (U.S. Pat. No. 5,989,581) in view of Zaffaroni (U.S. Pat. No. 3,948,254) and in view of Zaffaroni (U.S. Pat. No. 3,854,480) and further in view of Visser (U.S. Pat. No. 5,935,597).

The instant invention is drawn to a sustained release drug delivery system comprising: an inner drug core comprising an amount of antiviral agent; an inner tube impermeable to passage of said agent, said inner tube having first and second ends and covering at least a portion of said drug core, said inner tube being dimensionally stable; an impermeable member positioned at said inner tube first end, said impermeable member preventing passage

of said agent out of said drug core through said inner tube first end; and a permeable member positioned at said inner tube second end, said permeable member allowing diffusion of said agent from said drug core through said inner tube second end.

Groenewegen ('581) teaches a co-axial fiber wherein the fiber having two ends comprises a drug reservoir for primarily administering contraceptives (see Examples and column 3, line 60 – col. 4, line 4). The coaxial formulation constitutes a device having an inner tube and an outer layer (thermoplastic skin) covering said drug reservoir. The material forming the fiber comprises ethylene vinylacetate copolymer (col. 3, lines 25-37); (col. 4, lines 5-22). One skilled in the art would immediately envision various configurations for the fiber components such that the requisite degree of permeability is present to enable the desired rate of sustained drug release (col. 4, line 23 – col. 5, line 3). Groenewegen teaches that the skin is permeable to the agent.

Groenewegen do not teach impermeability of the inner tube or layer.

Zaffaroni ('254) teach a drug delivery device comprising two different walls surrounding a reservoir containing a drug, whereby one wall (16) is formed of a material that is impermeable to the passage of drug (see reference column 4, lines 9-11); (col. 5, lines 11-14) and Figure 2. Zaffaroni also teaches that for highly water-soluble drugs, it is preferable that the wall or the reservoir, or both, be formed from a material that is substantially impermeable to water to essentially prevent dilution of the drug (col. 19, lines 10-15).

It is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate and incorporate a drug delivery device comprising an impermeable layer or wall so as to prevent passage of an active agent, such as taught by Zaffaroni within the drug delivery device of Groenewegen in order to provide for an effective drug release rate-controlling mechanism for the device. The expected result would be a drug delivery device whereby the configuration of the coating layers could be easily adjusted to provide for desired sustained rates of release.

With regards to the instant amounts claimed, such as the instant amounts of active agent, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, amounts and/or ranges are routine-optimized variables capable of being determined by one of ordinary skill in the art through manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

The teachings of Groenewegen ('581) and Zaffaroni ('254) are delineated above. Groenewegen and Zaffaroni do not teach antiviral agents.

Zaffaroni ('480) teaches a drug delivery system for releasing drug at a controlled rate for a prolonged period of time, whereby suitable drugs for use in the system include antivirals, such as idoxuridine (see reference column 5, lines 54-56 and Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antiviral agents (i.e., idoxuridine), as taught by Zaffaroni ('480) in the device of Groenewegen or Zaffaroni ('254), since Zaffaroni ('480) teach antiviral agents (*i.e.*, idoxuridine) and teach that antiviral agents are suitable drugs for use in therapy with the drug delivery device. The expected result would be an effective and improved drug delivery device that provides for the controlled release of drugs, such as antivirals.

The teachings of Groenewegen ('581), Zaffaroni ('254) and ('480) are discussed above. They do not teach the antiviral – nevirapine.

Visser ('597) teach drug delivery devices and methods for treating viral and microbial infections comprising active agents effective for the treatment of such viral or microbial conditions (see Abstract); (col. 1, lines 13-24). Visser teach that active agents effective for the treatment of infection, such as HIV include nevirapine (col. 7, line 65 – col. 8, line 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antiviral agent - nevirapine, as taught by Visser within the devices of Zaffaroni ('480) and Zaffaroni ('254). One would be motivated to do so with a reasonable expectation of success because Visser teach drug delivery devices that utilize

antiviral agents, particularly, nevirapine and teach that nevirapine is an effective drug used for the beneficial treatment of viral infections and conditions. The expected result would be an enhanced drug delivery system that efficiently combats viral diseases for the user in need thereof.

* * * * *

Claims 1, 12-17 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni (U.S. Pat. No. 3,948,254) in view of Zaffaroni (U.S. Pat. No. 3,854,480) and further in view of Visser (U.S. Pat. No. 5,935,597).

The instant invention is drawn to a sustained release drug delivery system comprising: an inner drug core comprising an amount of antiviral agent; an inner tube impermeable to passage of said agent, said inner tube having first and second ends and covering at least a portion of said drug core, said inner tube being dimensionally stable; an impermeable member positioned at said inner tube first end, said impermeable member preventing passage of said agent out of said drug core through said inner tube first end; and a permeable member positioned at said inner tube second end, said permeable member allowing diffusion of said agent from said drug core through said inner tube second end.

Zaffaroni ('254) teach a drug delivery device comprising two different walls surrounding a reservoir containing a drug, whereby one wall (16) is formed of a material that is impermeable to the passage of drug (see reference column 4, lines 9-11); (col. 5, lines 11-

14) and Figure 2. Zaffaroni also teaches that for highly water-soluble drugs, it is preferable that the wall or the reservoir, or both, be formed from a material that is substantially impermeable to water to essentially prevent dilution of the drug (col. 19, lines 10-15). The reference also shows a drug delivery device wherein the reservoir may comprise an oblong mold. The outer surface constitutes the equivalent of Applicant's inner tube. The device is further coated with an outer layer. One skilled in the art would immediately envision the drug release rate controlling mechanism characteristic of the device. The manipulation or configuration of the pores in the coating layers would be easily adjusted by the skilled artisan to provide the desired sustained rate of release (see Examples 1-3, figure 1; and col. 1, lines 42-68). Particular drugs are shown in column 18.

Zaffaroni ('254) does not teach antiviral agents.

Zaffaroni ('480) teaches a drug delivery system for releasing drug at a controlled rate for a prolonged period of time, whereby suitable drugs for use in the system include antivirals, such as idoxuridine (see reference column 5, lines 54-56 and Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antiviral agents, such as idoxuridine, as taught by Zaffaroni ('480) in the device of Zaffaroni ('254), since Zaffaroni ('480) teach antiviral agents (*i.e.*, idoxuridine) and teach that antiviral agents are suitable drugs for use in therapy with the drug delivery device. The expected result would be a highly effective, controlled rate-release drug delivery device.

With regards to the instant amounts claimed, such as the instant amounts of active agent, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, amounts and/or ranges are routine-optimized variables capable of being determined by one of ordinary skill in the art through manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

The teachings of Zaffaroni ('254) and ('480) are discussed above. They do not teach the antiviral – nevirapine.

Visser ('597) teach drug delivery devices and methods for treating viral and microbial infections comprising active agents effective for the treatment of such viral or microbial conditions (see Abstract); (col. 1, lines 13-24). Visser teach that active agents effective for the treatment of infection, such as HIV include nevirapine (col. 7, line 65 – col. 8, line 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antiviral agent - nevirapine, as taught by Visser within the devices of Zaffaroni ('480) and Zaffaroni ('254). One would be motivated to do so with a reasonable expectation of success because Visser teach drug delivery devices that utilize antiviral agents, particularly, nevirapine and teach that nevirapine is an effective drug used

for the beneficial treatment of viral infections and conditions. The expected result would be an enhanced drug delivery system that efficiently combats viral diseases for the user in need thereof.

* * * * *

Claims 1, 12-17 and 21-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith *et al.* (U.S. Pat. No. 5,378,475) in view of Visser (U.S. Pat. No. 5,935,597).

The instant invention is drawn to a sustained release drug delivery system comprising: an inner drug core comprising an amount of antiviral agent; an inner tube impermeable to passage of said agent, said inner tube having first and second ends and covering at least a portion of said drug core, said inner tube being dimensionally stable; an impermeable member positioned at said inner tube first end, said impermeable member preventing passage of said agent out of said drug core through said inner tube first end; and a permeable member positioned at said inner tube second end, said permeable member allowing diffusion of said agent from said drug core through said inner tube second end.

Smith *et al.* ('475) teach sustained release drug delivery devices and methods for treating a mammalian organism to obtain a desired local or systemic physiological or pharmacological effect. The device includes an inner core or reservoir comprising the effective agent; a first coating layer, which is essentially impermeable to the passage of the effective agent; and a second coating layer, which is permeable to the passage of the effective agent. the first coating layer covers at least a portion of the inner core; however, at least a portion of the inner core is not

coated with the first coating layer. The second coating layer essentially completely covers the first coating layer and the uncoated portion of the inner core (see Abstract); (col. 1, lines 5-20).

Smith et al. teach that the first layer must be selected to be impermeable to the passage of the agent from the inner core out to adjacent portions of the second coating layer. The purpose is to block the passage of the agent to those portions and thus control the release of the agent out of the drug delivery device (col. 7, lines 10-33).

Natural or synthetic materials that can be used in the device include cross-linked polyvinyl alcohol, plasticized nylon, silicone rubbers and the like (col. 6, lines 41-66). See also column 8, lines 49-68).

Smith does not teach the antiviral – nevirapine.

Visser ('597) teach drug delivery devices and methods for treating viral and microbial infections comprising active agents effective for the treatment of such viral or microbial conditions (see Abstract); (col. 1, lines 13-24). Visser teach that active agents effective for the treatment of infection, such as HIV include nevirapine (col. 7, line 65 – col. 8, line 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the antiviral agent - nevirapine, as taught by Visser within the devices of Smith. One would be motivated to do so with a reasonable expectation of success because Visser teach drug delivery devices that utilize antiviral agents, particularly, nevirapine and teach that nevirapine is an effective drug used for the beneficial treatment of

viral infections and conditions. The expected result would be an enhanced drug delivery system that efficiently combats viral diseases for the user in need thereof.

With regards to the instant amounts claimed, such as the instant amounts of active agent, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Furthermore, amounts and/or ranges are routine-optimized variables capable of being determined by one of ordinary skill in the art through manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N SHEIKH
PRIMARY EXAMINER

Art Unit 1615

December 18, 2007

hns